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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,205	05/02/2002	Richard A Gambale	B 0410/7284	4832

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BOSTON, MA 02109-1808

EXAMINER
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JACKSON, SUZETTE JAMIE

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/23/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
10/048,205	GAMBALE, RICHARD A	
Examiner	Art Unit	
Jackson J Suzette	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 02 May 2002.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 5-18 is/are rejected.
- 7) Claim(s) 4 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 May 2002 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> .	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

*Drawings*

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show elements “2”, mentioned on page 8, line 7; “28, mentioned on page 8, line 8 and “66” as described in the specification on page 6, line 17. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: “48”, “52”, “53”, “94”. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

*Specification*

3. The disclosure is objected to because of the following informalities: On page 5, line 6, there is no Figure 13 as mentioned in the specification. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 5, 8-10, 13-14, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Khosravi et al. 6,425,915. Khosravi et al discloses the invention as claimed (noting figures 5A-5B) including: A tissue implant device (40) configured to resist migration in tissue comprising: a flexible helical spring having at least one barb that engages surrounding tissue (it is inherent that the barbs are for engaging the tissue col. 9, line 7, to resist migration. See col. 8, lines 60-67); wherein the barb has a sharpened point; formed from a plurality of materials each having different moduli of elasticity (Nitinol is made of nickel-titanium alloy which equates to the plurality of materials with varying moduli); stainless steel (col. 6, lines 18-22); and methods of making including forming a ribbon shaped form in a sheet of material by photochemical etching process (col. 6, lines 25-29); separating the ribbon form from the sheet and wrapping the ribbon form into a helical coil shape (see col. 6, lines 36-43).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 6-7, 12-13, 15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. in view of Pinchuk 5,092,877. Khosravi et al. has been disclosed above with regards to claims 1, 3, 5, 8-10, 14, 18 however, the helical coil of Khosravi et al does not specify *a single filament* as stated in claims *6 and 12*. Pinchuk teaches a helical coil shaped filament (see figure 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the invention of Khosravi et al. and produce a helical coil filament because the same methodology exist known in forming spring coil prosthesis and that is to form a ribbon, thin band or filament from a sheet and chemical etch, laser, cut or punch the shape then form the helical prosthesis around a mandrel. Khosravi et al. does not specify *proximal facing barbs as stated in claims 2, 7, 15-16*. It would have been obvious to one having ordinary skill in the art at the time the invention was made to place the barb on the proximal facing edge of the coil and is a matter of design choice because the barbs of Khosravi serve the same purpose as claimed and that is to prevent migration of the prosthesis by engaging the intima of the tissue (see col. 9,lines 5-6).

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al. in view of Edwin et al. 6,053,943. Khosravi et al. has been disclosed above however Khosravi et al. does not teach that the moduli of elasticity of the spring varies along its length. Edwin et al. teaches a helical device with strain relief section having differential moduli of elasticity (see claim 7). It would have been obvious to one having ordinary skill in the art at the time the

invention was made to modify the helical coil device of Khosravi et al. to have differential moduli of elasticity in order to provide a flexible prosthesis that can contour to the tissue during expansion.

*Allowable Subject Matter*

9. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

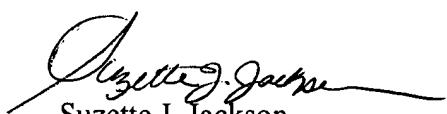
*Conclusion*

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Teoh 6,544,275; Panescu et al. 6,500,172 ; Bulver 6,494,907 ; Unsworth et al. 6,494,657 ; Makower et al. 6,491,707 ; Taheri 6,478,818 ; Thorud et al. 6,019,779 ; Mollenauer et al. 5,709,692 all show related subject matter.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

9. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3580.

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Suzette J. Jackson  
21 April 2003